Younes Sleep Technologies

K112102

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6.0 510(k) Summary

6.1 Background Information

510(k) Owner: Younes Sleep Technologies
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Date of Summary: October 16, 2011

Device Trade Name: MICHELE Sleep Scoring System
Device Common Name: Sleep Analysis System
Classification Name: Ventilatory Effort Recorder
Class: II
Product Code: MNR
Regulation Number: 21 CFR 868.2375

Indications for Use:

The MICHELE Sleep Scoring System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders.

The MICHELE Sleep Scoring System is intended to be used for analysis (automatic scoring and manual rescoring), display, redisplay (retrieve), summarize, reports generation and networking of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.

The device is to be used under the supervision of a physician. Use is restricted to files obtained from adult patients.

Predicate Devices to which Substantial Equivalence is Claimed:

1. Trade Name: Alice 5 System
   Respironics Inc.
   510(k) Number: K040595
   Classification Name: Electroencephalography/Polysomnography System
   Class: II
   Product Code: GWQ

	Regulation Number:	21 CFR 882.1400 Electroencephalograph
2.	Trade Name:	Morpheus™ 1, Automated Sleep Study Scoring and Data Management System WideMed Ltd.
	510(k) Number:	K022506
	Classification Name:	Ventilatory Effort Recorder
	Class:	II
	Product Code:	MNR
	Regulation Number:	21 CFR 868.2375 Breathing Frequency Monitor
3.	Trade Name:	Somnolyzer® 24x7 The Siesta Group North America
	510(k) Number:	K083620
	Classification Name:	Ventilatory Effort Recorder
	Class:	II
	Product Code:	MNR
	Regulation Number:	21 CFR 868.2375 Breathing Frequency Monitor

6.2 Device Description

6.2.1 How the Device Functions

The MICHELE Sleep Scoring System (MICHELE) is a software system that scans physiological data obtained during level 1 sleep studies, referred to as polysomnography (PSG) records, and applies a variety of analytical approaches to identify the occurrence of certain events that relate to the presence and type of sleep state, breathing abnormalities and limb movements. The system scores Sleep Stages, Arousals, Respiratory Events and Leg Movements. At the end of the analysis the system generates a PSG Report that includes tables and graphs typical of those generated following manual scoring of PSG records by certified technologists. The results of the automated scoring may be displayed using a PSG Scoring Viewer application, which allows manual editing of the results and generation of a revised PSG Report.

The device does not analyze data that are different from those analyzed by human scorers. It also neither interprets the results nor suggests a diagnosis.

6.2.2 Scientific Concepts that form the Basis for the Device

MICHELE is a standalone software system. It processes PSG records that consist of several channels of data recorded from patients during sleep, including electroencephalogram (EEG), Chin electromyogram (EMG), electrooculogram (EOG), electrocardiogram (ECG), leg EMG, chest and abdomen excursions measured

by respiratory bands, nasal cannula flow, thermister flow and oxygen saturation. It does not record data and therefore does not have direct contact with patients.

MICHELE has been designed to score Sleep Stages, Arousals, Respiratory Events and Leg Movements as a human certified technologist would, according to the standard guidelines of the American Academy of Sleep Medicine (AASM) described in *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, American Academy of Sleep Medicine, Westchester, IL, 2007.*

6.2.3 Significant Physical and Performance Characteristics

The system uses standard desktop computers with Windows XP (Service Pack 3) or Windows 7 operating systems. The programming environment is Visual Studio. Further details regarding software are presented in Section 17 of this 510(k) Notification.

The software performance was measured by: A) Determining epoch-by-epoch agreement between MICHELE's scoring and the scoring of three technologists with respect to the four scoring functions (Sleep staging, Arousals, Periodic Leg Movements (PLMs) and Respiratory Events) (Objective 1). B) Determining the agreement between MICHELE's results of Clinically Relevant Data, such as Total Sleep Time, Time in Different Stages, Apnea and Hypopnea Index (AHI...etc) and the results of the three technologists (Objective 2). MICHELE's performance, so determined, was compared with the results of analysis of the same validation files by one of the predicate devices, Alice 5 (K040595), using the same scoring guidelines (AASM 2007). It was also compared with the published performance of the two other predicate devices, Somnolyzer (K083620) and Morpheus (K022506).

6.2.3.1 Files: Software performance was assessed using 30 full night studies recorded in the sleep laboratory of a tertiary care facility (Foothills Hospital, Calgary, Canada). The files were selected at random and included 19 patients with sleep apnea. Fifteen of these patients had moderate to severe sleep apnea (AHI 73±38 hr^{-1}) and underwent split studies with one part (pre-CPAP) where sleep was severely fragmented and a second part (on CPAP) with fairly normal sleep and breathing. The group also included 9 patients with PLMs (8 to183 hr^{-1}; average 38±55 hr^{-1}), two patients with severe sleep fragmentation for no apparent cause (non-organic insomnia) and seven patients with normal sleep. Overall, the quality of sleep varied considerably among the 30 patients with Total Sleep Time ranging from 2.6 to 7.8 hours (4.2±1.1 hours), sleep efficiency ranging from 37 to 99% (61±18%) and arousal index ranging from 9 to 97 hr^{-1} (17±4 hr^{-1}). A total of 24967 thirty-second epochs were scored.

6.2.3.2 Technologists: Each of the three scorers is Board certified and has had at least 15 years of hands-on experience in scoring polysomnograms.

6.2.3.3 Analytical Methods and Results:

6.2.3.3.1 Objective 1 testing (epoch-by-epoch agreement). Table 6-1, left panels, shows results of epoch-by-epoch agreement between MICHELE and a consensus (≥2 of the scorers agree) of the three scorers. The right panels show the results for the predicate device to which it was possible to directly compare results, Alice 5, (referred to as Alice herein) using the same files and scoring guidelines. Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), Overall % agreement and Cohen's kappa (kappa) were calculated according to Altman DG et al (1). The weighted average of test and reference scorers was obtained for PPA (i.e. APPA) and NPA (i.e. ANPA).

APPA, ANPA, Overall % agreement and kappa obtained with MICHELE exceeded the corresponding values obtained with Alice for all comparisons.

6.2.3.3.1.1 Comparison with Other Predicate Devices:

There is only one study dealing with the performance of Morpheus (2). These authors reported on the agreement between Morpheus and two individual (i.e. not a consensus) technologists, M1 and M2, as well as the agreement between M1 and M2. The paper includes data on all four functions. Data available for sleep staging include agreement for 5-stage scoring along with PPA for each stage and the overall %agreement and kappa. They also provided %agreement and kappa, but not PPA, for 4-stage scoring (Awake, N1+N2, N3, Rem) and 3-stage scoring (awake, non-Rem and Rem). For scoring of arousals, PLM and respiratory events, they provided overall %agreement and kappa for scoring one event, two events or no events (3 x 3 matrix). There was no information on agreement for different categories of respiratory events.

Two studies are available for the Somnolyzer. In one (4), the authors reported on % agreement for sleep stages only, in comparisons between the Somnolyzer and a 2/3 consensus of technologists. Their subjects were mostly normal but the study included 25 patients with sleep apnea (severity unspecified). The % agreement and kappa values for sleep staging by MICHELE (82.6%, Table 6-1) exceeded the values reported in that study both for the apnea patients (75.6%) and the normal subjects (80.4%).

The other study on Somnolyzer (3) reported on %agreement and kappa in comparisons between the Somnolyzer and one scorer. Comparisons were limited to sleep staging, and the subjects were all normal.

In order to compare our results with those cited above (2,3) it was necessary to analyze and report our data in the same fashion (i.e. one-on-one comparisons between the Auto-score and two technologists and between the two technologists). This is presented below for our first two scorers (S1 and S2) along with the agreement indices that correspond to what they reported (Table 6-2).

TABLE 6-1
AGREEMENT BETWEEN AUTO-SCORING AND CONSENSUS (2/3) OF THREE TECHNOLOGISTS

SCORING FUNCTION	MICHELE					ALICE				
	Total by Techs.	APPA	ANPA	Overall % Agreement	kappa (%)	Total by Techs.	APPA	ANPA	Overall % Agreement	kappa (%)
SLEEP STAGING	**24967**			82.6	76.5	**24967**			30.5	5.9
Awake	6563	89.9	96.4			6563	5.4	85.1		
N1	2411	50.4	94.7			2411	2.3	94.6		
N2	9846	82.9	89.6			9846	42.1	51.2		
N3	2862	82.9	97.5			2862	34.7	73.9		
Rem	3285	89.8	98.5			3285	7.5	93.1		
No Consensus	283					283				
AROUSALS	**17648**			89.9	54.2	**17648**			57.9	10.0
Yes	2278	60.0	94.1			2278	28.1	70.3		
None	15370					15370				
No Consensus	104					104				
PLMs	**18461**			95.7	68.7	**18461**			88.3	38.2
Yes	1741	78.4	97.6			1741	44.7	93.4		
None	16720					16720				
No Consensus	47					47				
RESPRIRATORY EVENTS										
Criteria A	**17746**			94.0	74.2	**17746**			78.0	24.7
Hypopnea	1513	76.3	96.6			1513	9.3	95.3		
Obstructive Apnea	329	57.1	99.2			329	14.8	92.0		
Mixed Apnea	214	79.4	99.7			214	34.8	99.1		
Central Apnea	174	64.9	99.6			174	16.7	99.1		
None	15516	96.9	89.1			15516	90.1	48.0		
No Consensus	132					132				
Criteria B	**17824**			93.0	70.4	**17824**			75.9	23.1
Hypopnea	1822	60.3	97.6			1822	5.1	94.1		
Obstructive Apnea	359	55.9	99.3			359	15.5	91.7		
Mixed Apnea	214	83.6	99.6			214	34.2	99.1		
Central Apnea	177	63.8	99.6			177	16.6	98.9		
None	15252	98.1	75.5			15252	89.0	47.7		
No Consensus	133					133				

Numbers in Sleep Staging rows are number of 30-second epochs. Numbers in Event rows are numbers of events and not epochs except in the "None" category where the number refers to number of epochs with no events.
APPA, Averaged Positive Percent Agreement; ANPA, Averaged Negative Percent Agreement; N1, N2, and N3, Non-Rem stages 1, 2 and 3; PLMs, Periodic Limb Movements; No Consensus, all three technologists gave different scores.

Table 6-2 shows that the agreement between MICHELE and individual technologists equals or exceeds the corresponding values in the Morpheus study (2). It is to be noted that the criteria for scoring respiratory events used in the Morpheus study (the Chicago criteria (5)) were different from the criteria used in our study (AASM criteria (6)), and that the latter criteria are more complex than the former. It is also notable that the agreement between MICHELE and each of the two technologists (S1 and S2) is substantially comparable to the agreement between the two technologists. The other published study dealing with the Somnolyzer (3) reported a % agreement of 72.3% with a kappa of 59.1% for agreement between the Somnolyzer and one scorer in staging sleep. The agreement between MICHELE and either technologist (S1 or S2) exceeds their reported value.

TABLE 6-2

COMPARISON OF MICHELE SLEEP SCORING SYSTEM AND MORPHEUS

Scoring Function	Test reported	MICHELE Sleep Scoring System			Morpheus (2)		
		Auto vs.S1	Auto vs. S2	S1 vs S2	Auto vs.M1	Auto vs. M2	M1 vs M2
SLEEP (5-stage)	%agreement (kappa)	80.9(74.4)	76.7(68.4)	79.6(72.3)	77.7(67.0)	73.3(61.0)	82.1(73.0)
Awake	PPA	94.4	82.6	75.0	68.7	69.6	80.9
N1	PPA	41.4	41.9	53.6	13.1	19.9	21.3
N2	PPA	80.9	76.1	82.9	73.5	68.9	77.1
N3	PPA	89.7	89.2	90.5	58.0	35.3	47.7
Rem	PPA	87.3	85.8	94.2	60.7	57.1	79.0
SLEEP (4-stage)	%agreement (kappa)	88.0(81.8)	83.3(74.6)	84.9(76.6)	82.6(71.0)	79.9(65.0)	88.7(80)
SLEEP (3-stage)	%agreement (kappa)	91.4(83.5)	91.1(81.8)	90.8(82.8)	88.0(75.0)	88.0(74.0)	93.5(87.0)
AROUSALS (3X3)	%agreement (kappa)	84.1(38.8)	87.9(49.3)	85.7(46.4)	76.2(28.0)	76.1(30.0)	83.7(57.0)
PLMs (3X3)	%agreement (kappa)	95.0(66.2)	94.6(67.0)	93.8(60.2)	93.1(68.0)	92.2(66.0)	95.6(77.0)
RESPRIRATORY							
Chicago (3X3)	%agreement (kappa)				89.7(66.0)	89.7(66.0)	94.9(82.0)
Criteria A (3X3)	%agreement (kappa)	94.8(78.3)	94.6(75.2)	94.9(76.4)			
Criteria B (3X3)	%agreement (kappa)	94.3(76.5)	93.9(71.7)	93.8(74.3)			

6.2.3.3.2 Objective 2 testing:

In this section we discuss agreement between automatic and manual scoring for summary variables that appear in the clinical report used by physicians to assess sleep disorders. Table 6-3 shows the results for 14 variables. These were selected because they are the most commonly used variables in the clinical assessment.
The first data Column of Table 6-3 is the average score of the three technologists for each of the 14 variables of interest. The averaging was done on a file-by-file basis. The values and corresponding standard deviations (SD) given in column 1 are the average and SD of the 30 averages. The second column contains the average and SD of the values obtained from automatic analysis with MICHELE Sleep Scoring System. The third column lists the average and SD of the thirty differences between MICHELE and the corresponding average of the three technologists (Bland and Altman analysis).

The fourth and fifth columns are the corresponding results for the predicate device (Alice). Shaded cells in columns 3 and 5 indicate significant difference ($p \leq 0.05$) between the Auto-score (MICHELE or Alice) and the average of the three technologists. The last five columns contain the intra-class correlation coefficients for comparisons between each of the five scorers and the average score of the three technologists.

The results show good agreement in general between MICHELE scores and the average of three technologists. With the exception of the arousal index where concordance (ICC) between the Auto-score and the average was only modest (ICC = 0.566), concordance was excellent and mostly within the range observed in comparisons between individual technologists and the average of the three technologists. Average ICC for MICHELE vs. average of three technologists was 0.918 (bottom row, Table 6-3), only marginally below S1 ($p=0.03$ by ANOVA for repeated measures) and not significantly different from S2 or S3.

The results for analysis with the predicate device (Alice) are also shown in Table 6-3. It is clear that MICHELE's performance is superior in all respects. Alice found no Rem sleep in 27 of the 30 files, even though Rem was present in 28 of the files as identified by each of the three technologists and by MICHELE.

6.2.3.3.2.1 Comparison with Other Predicate Devices:

Table 6-4 shows results for MICHELE (left 6 columns) and the only results available in the literature for another predicate device (Morpheus) (2). The first three columns in each set are the average results for the two human scorers (S1 and S2 in the case of MICHELE, and M1 and M2 for Morpheus) and the corresponding automatic score. The next three columns are intra-class correlation coefficients (ICC) for the relation between the Auto-score and the two technologists as well as the relation between the two technologists.

Table 6-3: Agreement between Manual and Automatic Scoring for Relevant Scoring Variables

Variable	Average	Michele		Alice		Intra-class Correlation Coefficients				
	S1-S3 SD	Michele SD	- ave. SD	Alice SD	- ave. SD	Michele vs. Ave.	Alice vs.Ave.	S1 vs. Ave.	S2 vs. Ave.	S3 vs. Ave.
Total sleep time (min)	312 74	312 72	0 13	440 66	128 96	0.983	-0.226	0.954	0.978	0.992
Sleep efficiency (%)	74.6 17.0	74.7 16.6	0.1 2.9	97.0 11.0	23.0 21.0	0.985	-0.243	0.957	0.98	0.994
Sleep-onset latency (min)	24 27	24 29	0 9	1 2	-24 27	0.950	-0.118	0.991	0.997	0.995
REM-onset latency (min)	126 71	126 73	0 28	NA	NA	0.923	NA	0.988	0.966	0.992
Stage wake (min)	108 76	108 74	-1 12	12 43	-97 88	0.986	-0.229	0.958	0.98	0.994
Stage 1 (min)	47 30	42 28	-5 14	3 9	-44 29	0.876	-0.219	0.912	0.864	0.91
Stage 2 (min)	165 54	159 50	-5 20	233 104	69 131	0.922	-0.288	0.983	0.964	0.972
Stage 1+ 2 (min)	212 57	202 62	-10 21	236 107	24 132	0.923	-0.192	0.951	0.935	0.95
Stage delta (min)	47 38	60 46	13 17	193 101	147 100	0.869	-0.132	0.940	0.847	0.948
Stage REM (min)	53 26	51 26	-2 8	3 14	-50 28	0.951	-0.282	0.988	0.977	0.984
Arousal Index (hr^{-1})	33 23	25 11	-9 15	54 18	21 31	0.566	-0.251	0.937	0.956	0.932
PLM Index (hr^{-1})	12 29	13 31	1 9	43 42	29 30	0.958	0.589	0.978	0.855	0.867
AHI A (hr^{-1})	30 41	32 40	2 7	34 22	4 34	0.982	0.369	0.992	0.974	0.988
AHI B (hr^{-1})	31 42	27 36	-4 8	30 21	-2 35	0.971	0.384	0.99	0.967	0.986
Average						0.918	-0.064	0.966	0.946	0.965

Table 6-4
Comparison between Michele and Morpheus for Scoring Clinically Relevant Variables

Variable	Michele Sleep-Scoring System						Morpheus					
	S1	S2	Auto	S1 vs. S2	S1 vs. Auto	S2 vs. Auto	M1	M2	Auto	M1 vs. M2	M1 vs. Auto	M2 vs. Auto
Total sleep time (min)	330	300	312	0.876	0.934	0.968	348	345	357	0.980	0.920	0.940
SD	*73*	*76*	*72*				*63*	*61*	*65*			
Sleep efficiency (%)	79	72	75	0.883	0.941	0.968	83	82	85	0.960	0.870	0.910
SD	*16*	*18*	*17*				*12*	*11*	*12*			
Sleep-onset latency (min)	22	25	24	0.98	0.94	0.95	26	26	22	1.000	0.860	0.860
SD	*27*	*27*	*29*				*24*	*24*	*21*			
REM-onset latency (min)	131	121	126	0.92	0.90	0.92	130	127	175	0.990	0.460	0.460
SD	*72*	*71*	*73*				*79*	*74*	*81*			
Stage wake (min)	91	120	108	0.886	0.942	0.969	85	89	76	0.960	0.870	0.910
SD	*72*	*80*	*74*				*49*	*46*	*50*			
Stage 1 (min)	52	44	42	0.692	0.731	0.804	19	49	38	0.220	0.370	0.530
SD	*40*	*29*	*28*				*15*	*20*	*27*			
Stage 2 (min)	167	168	159	0.925	0.926	0.822	231	222	214	0.800	0.840	0.720
SD	*57*	*57*	*50*				*54*	*46*	*48*			
Stage 1+ 2 (min)	219	212	202	0.830	0.903	0.811	250	270	252	0.860	0.870	0.730
SD	*62*	*61*	*62*				*55*	*53*	*59*			
Stage delta (min)	55	36	60	0.671	0.967	0.548	38	21	50	0.570	0.530	0.180
SD	*43*	*36*	*46*				*26*	*23*	*26*			
Stage REM (min)	55	51	51	0.948	0.953	0.915	60	53	55	0.920	0.720	0.760
SD	*28*	*25*	*26*				*30*	*26*	*34*			
Arousal Index (events/h)	32	33	25	0.875	0.594	0.461	30	36	22	0.810	0.720	0.580
SD	*18*	*24*	*11*				*19*	*17*	*16*			
PLM Index (events/h)	11	12	13	0.849	0.959	0.738	13	16	19	0.930	0.610	0.650
SD	*31*	*32*	*31*				*19*	*21*	*25*			
Resp. Disturbance Index							21	23	24	0.990	0.950	0.950
SD							*23*	*25*	*23*			
AHI A (events/h^{-1})	30	28	32	0.947	0.985	0.930						
SD	*40*	*41*	*40*									
AHI B (events/h^{-1})	34	31	29	0.932	0.967	0.926						
SD	*43*	*43*	*37*									
Average				0.872	0.903	0.838				0.845	0.738	0.706

Significantly different from Auto. Significantly different from Tech.2.
Significantly different from both Tech. 2 and Auto.

As may be expected from comparisons involving a large number of pairs, and as shown in Table 6-4 by highlighted cells, there were many significant differences between the three scorers even though the average differences were small. The results

of Morpheus were significantly different from both M1 and M2 in eight variables (solid shade and diagonal stripes). MICHELE Auto-scoring was different from both S1 and S2 in five. As in the case of the MICHELE, the authors of the Morpheus study (2) commented on the occasional inaccuracy of the Morpheus system in estimating Rem-onset latency. They indicated that Morpheus missed the first Rem period in 10 patients (32%) whereas MICHELE missed the first Rem period in only one patient. The differences they reported between manual and automatic scoring in the other variables were in the same range as what we observed with MICHELE. Both systems underestimated the arousal index. With Morpheus the difference was 11 hr^{-1} (0.5[30+36]-22) while MICHELE underestimated the index by 8 hr^{-1} {0.5[32+33]-25). The correlation coefficients for comparisons between manual and MICHELE's scoring (S1 vs. Auto and S2 vs. Auto)) exceeded the corresponding coefficients in the Morpheus study (M1 vs. Auto and M2 vs. Auto)) in all categories except the Arousal Index, where it was only marginally lower. The averages of all correlation coefficients for the comparisons between Tech.1&Tech.2, Tech.1 vs. Auto and Tech.2 vs. Auto are given at the bottom of Table 6-4. There were no significant differences (by ANOVA for repeated measures) between the three averages in the case of MICHELE.

6.3 Comparison of Indications for Use Statements

The following table compares Indications for Use Statements between the MICHELE Sleep Scoring System, and the three predicate devices, i.e. Alice 5, Somnolyzer® 24x7 and Morpheus™ 1, Automated Sleep Study Scoring and Data Management System (referred to as Morpheus™ in the table).

Similar to the other two predicate devices, the principal predicate device used for direct comparison, Alice 5, automatically scores polysomnography data based on user-specified criteria, and reports findings about sleep stages, arousals, periodic limb movements, and respiratory events in a conventional PSG report. The user may edit the automatic scoring but the report can be printed with or without editing.

Table 6-5: Comparison of Indications for Use Statements

	MICHELE	ALICE 5	SOMNOLYZER® 24x7	Morpheus™
Indications for Use	The MICHELE Sleep Scoring System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders. The MICHELE Sleep Scoring System is	The Alice 5 System is a Polysomnography System that is intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically	Somnolyzer 24X7 is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders. Somnolyzer 24X7 is intended to be used for analysis	The Morpheus™ 1 Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid for the diagnosis of sleep and

	MICHELE	ALICE 5	SOMNOLYZER® 24x7	Morpheus™
	intended to be used for analysis (automatic scoring and manual rescoring), display, redisplay (retrieve), summarize, reports generation and networking of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. The device is to be used under the supervision of a physician.	on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other environments where adults or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and, is not intended for use as an automated apnea monitor. (From 510k Number K040595)	(automatic scoring and manual rescoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. This device is to be used under the supervision of a physician. (From 510k Number K083620)	respiratory disorders. The Morpheus™ 1 Automated Sleep Study Scoring and Data Management System is intended to be used for analysis (automatic scoring and manual rescoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. This device is to be used under the supervision of a physician. (From 510k Number K022506)

6.4 Comparison of Technological Characteristics

The following table compares characteristics between MICHELE and the three predicate devices, i.e. the Alice 5, Somnolyzer® 24x7 and Morpheus™. The comparison demonstrates that MICHELE is substantially equivalent to the predicate devices considering the essential characteristics identified in the table.

Table 6-6: Comparison of Technological Characteristics

	MICHELE	ALICE 5	Somnolyzer® 24x7	MORPHEUS ™
Clinical Criteria:				
Clinical condition or purpose: Diagnosis of sleep and respiratory disorders	X	X	X [7]	X [8]
Population: Human subjects	X	X	X [9]	X [2]

	MICHELE	ALICE 5	Somnolyzer® 24x7	MORPHEUS ™
undergoing sleep studies				
Five-stage Sleep Stage Scoring (wake, Rem, three non-Rem stages)	X	X	X [3]	X [2]
Arousal Scoring	X	X [11]	X [9]	X [2]
Respiratory Events Scoring	X	X [11]	X [9]	X [2]
Leg Movements Scoring	X	X [11]	X [9]	X [2]
Performance assessed by percent agreement (and Cohen's kappa) between automatic and human scoring	X	X [11]	X [6]	X [2]
Basic operation: processing of polysomnography data recorded from patients in sleep laboratories and polysomnography report generation	X	X [11]	X [9]	X [10]
Data inputs for Sleep Stage and Arousal Scoring:				
Central electroencephalogram (EEG)	X	X [11]	X [9]	X [2]
Left and right eye electrooculogram (EOG)	X	X [11]	X [9]	X [2]
Chin electromyogram (EMG)	X	X [11]	X [9]	X [2]
Electrocardiogram (ECG)	X	X [11]	X [4]	X [2]
Data inputs for Respiratory Events Scoring:				
Chest and abdomen movements measured by respiratory bands	X	X [11]	X [4]	X [2]
Oxygen saturation	X	X [11]	X [4]	X [2]
Respiratory airflow	X	X [11]	X [4]	X [2]
Thermister	X	X [11]		X [2]
Audio	X	X [11]		X [2]
Body position	X	X [11]		X [2]
Airway CO2	X			
Airway pressure	X	X [11]		
Data inputs for Leg Movements Scoring:				
EMG recorded from right and left legs	X	X [11]	X [4]	X [2]
Additional Technical Criteria:				
Polysomnography records scored per 30 second epoch	X	X [11]	X [4]	X [2]
Cardiac artifacts removed from EEG, EMG and EOG channels	X			X [2]

6.5 Description and Conclusions of Testing

MICHELE has been tested as described in Section 17 of this 510(k) Notification. Testing is an integral part of YST's software development process as described in the company's product development process.

The successful non-clinical testing demonstrates the safety and effectiveness of MICHELE when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as the legally marketed predicate devices.

REFERENCES:

[1] Altman DG, Machin D, Bryant TN, Gardner MJ. Statistics With Confidence. British Medical Journal 2000.
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[4] Anderer P *et al.* (2005), "An E-Health Solution for Automatic Sleep Classification according to Rechtschaffen and Kales: Validation Study of the Somnolyzer 24 x 7 Utilizing the Siesta Database," Neuropsychobiology 51:115-133
[5] Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The report of an American Academy of Sleep Medicine Task Force. Sleep 22: 667–689, 1999.
[6] The AASM Manual for the Scoring of Sleep and Associated Disorders. American Academy of Sleep Medicine, Westchester, Illinois. 2007
[7] 510(k) Summary, K083620, for The Siesta Group Somnolyzer 24x7
[8] 510(k) Summary, K022506, for the WideMed Ltd. MorpheusTM 1, Automated Sleep Study Scoring and Automated Data Management System
[9] Siesta Group website, http://www.thesiestagroup.com/index.php?id=167
[10] WideMed Ltd. website, http://www.widemed.com/
[11] Alice 5 User Manual

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Magdy Younes
President
Younes Sleep Technologies
435 Ellice Avenue
Winnipeg, Manitoba
CANADA R3B 1Y6

DEC 2 0 2011

Re: K112102
Trade/Device Name: MICHELE Sleep Scoring System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 17, 2011
Received: December 16, 2011

Dear Mr. Younes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MICHELE Sleep Scoring System

Indications for Use:

The MICHELE Sleep Scoring System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders.

The MICHELE Sleep Scoring System is intended to be used for analysis (automatic scoring and manual rescoring), display, redisplay (retrieve), summarizing, reports generation and networking of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.

The device is to be used under the supervision of a physician. Use is restricted to files obtained from adult patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112102